U.S.S.N. 08/924,994
Filed: September 5, 1998
AMENDMENTS PURSUANT TO 37 C.F.R. § 1.121

It is believed that no additional fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 50-1868.

In the abstract

Page 26, please delete lines 12-14, "In the most preferred embodiment, the assay is an ELISA assay performed using Serex laminated strip format as described in U.S. patent Nos. 5,710,009, 5,500,375, and 5,451,004. These strips are advantageous since they serve as the collection and assay device."

In the Claims

1. (Amended) A method for [detection of] determining the level of an apolipoprotein in saliva comprising reacting the saliva with antibodies immunoreactive with the apolipoprotein in a quantitative assay, detecting the amount of immunoreactivity, and comparing the amount of immunoreactivity with standards to determine the level of apolipoproteins in the saliva.

4. (Amended) The method of claim 1 wherein the antibodies are labelled with a detectable [lable] label.

6. (Amended) The method of claim 1 wherein the saliva is prepared prior to testing to remove mucopolysaccharides from the saliva.

9. (Amended) The method of claim 8 further comprising normalizing the amount of the apoplipoprotein to the amount of albumin present in the saliva of the individual from whom the saliva was obtained.

12. An assay device or kit for determining the amount of apolipoprotein in a saliva sample comprising means for collection of saliva and antibodies immunoreactive with an apolipoprotein for use in a quantitative assay, and means for comparing the levels of the apolipoproteins in the saliva with the levels in serum.

13. (amended) The assay device or kit of claim 12 comprising filter means for removal of [mucopolysaccharide] mucopolysaccharides from the saliva.

16. (Amended) The assay device or kit of claim 12 wherein the antibodies are [contained on or] immobilized on a solid support.

18. (Amended) The assay device or kit of claim 12 comprising a strip or dipstick.

19. (Amended) The assay device or kit of claim 15 comprising as separate reagents antibodies to [an] the apolipoprotein and antibodies to albumin.

20. (Amended) A method for quantitating the amount of lipoprotein or cholesterol in saliva or determining the presence of lipid disorders or risk of cardiovascular disease comprising reacting a saliva sample with antibodies specifically immunoreactive with apolipoprotein selected from the group consisting of Apo A, Apo B, Apo C, Apo E, and components thereof in a quantitative assay.

21. (New) The method of claim 1 further comprising,

determining the correlation between the levels of HDL and/or LDL and the levels of apoprolipoproteins in serum, and

determining the levels of HDL and/or LDL in the serum, based on the measurements of the levels of the apolipoproteins in the saliva.

22. (New) The method of claim 20 comprising quantitating the amount of lipoprotein or cholesterol in saliva or determining the presence of lipid disorders or risk of cardiovascular disease by reacting a saliva sample with antibodies specifically immunoreactive with an apolipoprotein selected from the group consisting of Apo A, Apo B, Apo C, Apo E, and components thereof, and

correlating the levels of at least one apolipoprotein in the saliva with the levels in serum associated with the presence of lipid disorders or risk of cardiovascular disease.

23. (New) The method of claim 20 wherein the measurements of the apolipoproteins in serum are normalized against the level of albumin in the saliva as compared to the level of albumin in serum from the individual.

Remarks

The Abstract

The abstract has been amended to delete the reference to an issued U.S. Patent.

Rejection Under 35 U.S.C. § 112

Claims 1-20 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 has been amended to recite a detection and correlation step. However, MPEP § 2172.01 states that "[a] claim which omits matter disclosed to be essential to the invention as described in the specification or in other statements of record may be rejected under 35 U.S.C. 112, first paragraph, as not enabling... Such essential matter may include missing elements, steps